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Safety Indices of Ultrasound: Adherence to Recommendations and Awareness During Routine Obstetric Ultrasound Scanning

Sicherheitsindizes im Ultraschall: Einhaltung der Empfehlungen und Aufmerksamkeit beim Routine-Ultraschall in der Geburtshilfe

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Key words

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ABSTRACT

Purpose To analyze bioeffect safety indices and assess how often operators look at these indices during routine obstetric ultrasound.

Materials and Methods Automated analysis of prospectively collected data including video recordings of full-length ultrasound scans coupled with operator eye tracking was performed. Using optical recognition, we extracted the Mechanical Index (MI), Thermal Index in soft tissue (TIs), and Thermal Index in bone (TIb) values and ultrasound mode. This allowed us to report the bioeffect safety indices during routine obstetric scans and assess adherence to professional organization recommendations. Eye-tracking analysis allowed us to assess how often operators look at the displayed bioeffect safety indices.

Results A total of 637 ultrasound scans performed by 17 operators were included, of which 178, 216, and 243 scans were first, second, and third-trimester scans, respectively. During live scanning, the mean and range were 0.14 (0.1 to 3.0) for TIb, 0.2 (0.1 to 1.2) for TIs, and 0.9 (0.1 to 1.3) for MI. The mean and standard deviation of TIb were 0.15 ± 0.03, 0.23 ± 0.09, 0.32 ± 0.24 in the first, second, and third trimester, respectively. For B-mode, the highest TIb was 0.8 in all trimesters. The highest TIb was recorded for pulsed-wave Doppler mode in all trimesters. The recommended exposure times were maintained in all scans. Analysis of eye tracking suggested that operators looked at bioeffect safety indices in only 27 (4.2 %) of the scans.

Conclusion In this study, recommended bioeffect indices were adhered to in all routine scans. However, eye tracking showed that operators rarely assessed safety indices during scanning.

ZUSAMMENFASSUNG

Ziel Analyse der Bioeffekt-Sicherheitsindizes und Bewertung, wie häufig Anwender diese Indizes beim Routine-Ultraschall in der Geburtshilfe betrachten.

Material und Methoden Durchführung einer automatisierten Analyse prospektiv gesammelter Daten einschließlich der Videoaufnahmen von Ultraschalluntersuchungen in voller Länge, gekoppelt mit einem Eye-Tracking des Anwenders. Mithilfe optischer Erkennung wurden die Werte des mechanischen Index (MI), thermischen Index im Weichteilgewebe (TIs) und thermischen Index im Knochen (TIb) sowie der Ultraschallmodus extrahiert. Dadurch konnten wir die Bioeffekt-Sicherheitsindizes bei geburtshilflichen Routineuntersuchungen angeben und die Einhaltung der Empfehlungen der Berufsorganisation beurteilen. Die Analyse des Eye-Trackings ermöglichte es uns zu beurteilen, wie oft die Anwender die angezeigten Bioeffekt-Sicherheitsindizes betrachten.

Ergebnis Insgesamt wurden 637 Ultraschalluntersuchungen von 17 Anwendern eingeschlossen, von denen 178 im ersten, 216 im zweiten und 243 Untersuchungen im dritten Schwangerschaftstrimenon durchgeführt wurden. Bei der Live-Untersuchung lagen Mittelwert und Bereich des TIb bei 0,14 (0,1 bis 3,0), des TIs bei 0,2 (0,1 bis 1,2) und des MI bei 0,9 (0,1 bis 1,3). Mittelwert und Standardabweichung des TIb

* Lior Drukker and Richard Droste had equal contribution.

betrugen 0,15 ± 0,03 im ersten, 0,23 ± 0,09 im zweiten und 0,32 ± 0,24 im dritten Trimenon. Für den B-Modus lag der höchste TIb in allen Trimenons bei 0,8. Der höchste TIb wurde für den gepulsten Doppler-Modus in allen Trimenons gemessen. Die empfohlenen Expositionszeiten wurden bei allen Scans eingehalten. Die Analyse des Eye-Trackings ergab, dass die Anwender nur bei 27 Scans (4,2 %) auf die Bioeffekt-Sicherheitsindizes achteten.

Schlussfolgerung In dieser Studie wurden die empfohlenen Bioeffekt-Indizes bei allen Routine-Scans eingehalten. Die Eye-Tracking-Methode zeigte jedoch, dass die Anwender die Sicherheitsindizes während der Untersuchung nur selten analysieren.

Introduction

Animal studies suggest that prenatal ultrasound may produce biological effects on the exposed fetus [1, 2]. However, no consistent causal relationship between the proper use of diagnostic ultrasound and human biological effects (bioeffects) has been established [3, 4] apart from a weak association between ultrasound screening during pregnancy and non-right-handedness in later life [5].

The interaction between ultrasound and tissue generates thermal and mechanical effects. The thermal effect is tissue heating due to the transformation of acoustic energy into heat. The mechanical effect is, in particular, a cavitation effect of microscopic, stabilized gas bubbles in the tissues due to direct tissue reaction to alternating positive and negative pressure. As gas bubbles do not seem to be present in fetuses, the risk of mechanical effects is believed to be minimal [6].

The Thermal Index (TI) was designed to indicate the risk of tissue heating, while the Mechanical Index (MI) indicates the risk of inducing cavitation. In obstetrics, TI is reported in two variants: Thermal Index in soft tissue (TIs), which assumes that sound is traveling only in soft tissue and is monitored in early pregnancy when bone ossification is low; Thermal Index in bone (TIb), which assumes that sound is at or near the bone. The presence of bone within the ultrasound beam increases the likelihood of an increase in temperature due to direct absorption in the bone itself and conduction of heat from bone to adjacent tissue [7, 8]. Therefore, after ten weeks of gestation, it is recommended that TIb is used [9]. The real-time display of the TI and MI is colloquially known as the Output Display Standard (ODS) which was designed to provide the operator with quantitative safety-related information [10]. As part of training, ultrasound operators learn about potential bioeffects of ultrasound, and how to monitor these indices while scanning. Nevertheless, knowledge of bioeffects and their output indices is lacking among ultrasound operators [11, 12].

The aims of this study were to assess values of safety indices in routine obstetric ultrasound practice; to assess the adherence to professional guidelines[13, 14]; and to evaluate how frequently on-screen displays are assessed by operators. This was achieved by automated analysis of recordings of full-length ultrasound scans with concurrent operator eye movement tracking.

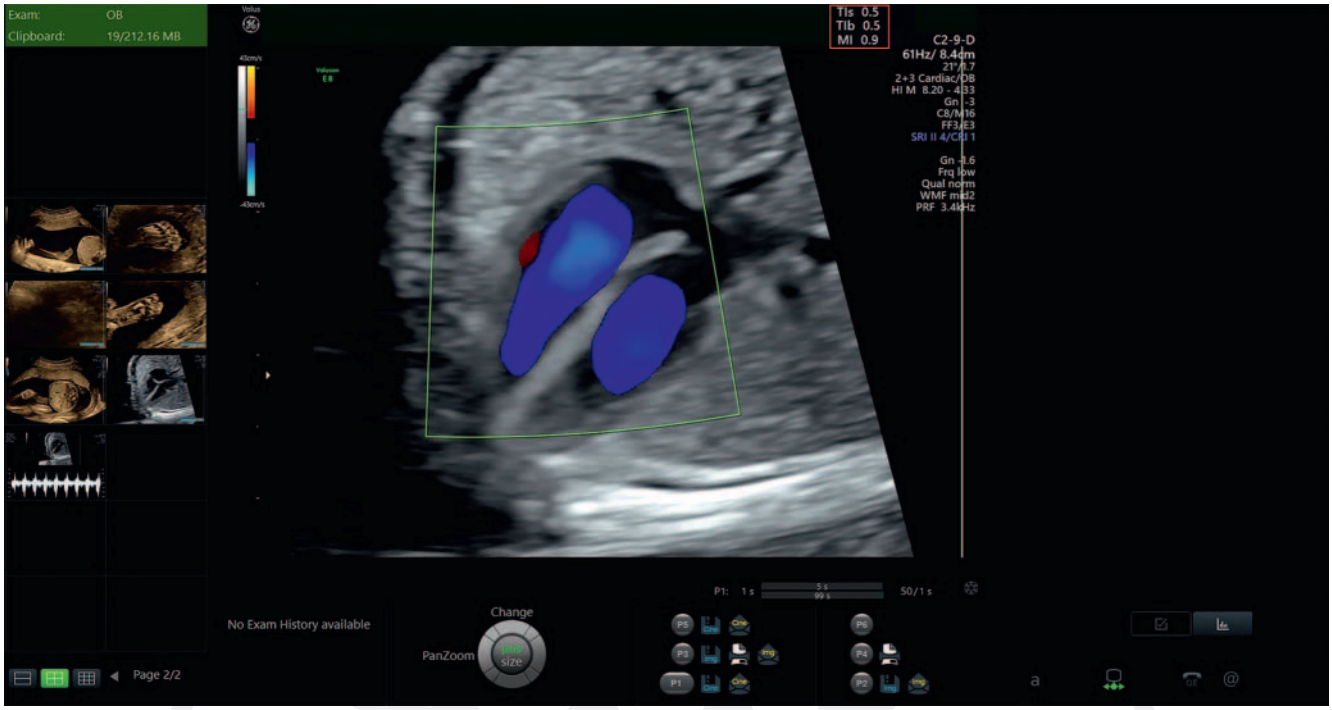
Methods

This was a prospective study of routine ultrasound scans performed in all trimesters between May 2018 and March 2019 by sonographers and fetal medicine doctors at the maternity ultrasound unit, Oxford University Hospitals NHS Foundation Trust, Oxfordshire, United Kingdom. Here, all women are offered three routine ultrasound scans: first-trimester dating at approximately 12 weeks which includes nuchal translucency measurement for first-trimester aneuploidy screening, a 20-week anomaly scan, and a 36-week growth scan. Additionally, based on risk factors or clinical indication, women may be offered additional scans at other gestational ages [15]. Ultrasound examinations are carried out or supervised by accredited sonographers or fetal medicine doctors using standard ultrasound equipment. For quality control measures, the stored images and the reliability of measurements are regularly assessed using the INTERGROWTH-21st quality criteria [16]. In the United Kingdom, color Doppler and pulsed-wave Doppler are not routinely employed as a part of first-trimester screening for trisomies [17]. Nevertheless, some operators are familiar with such advanced sonographic screening strategies [18] and may, therefore, choose to use Doppler and pulsed-wave Doppler as part of first-trimester screening [19–22].

This study is part of project entitled Perception Ultrasound by Learning Sonographic Experience (PULSE) [23]. This is an innovative interdisciplinary project that is designed to apply the latest ideas from machine learning and computer vision to build, from real-world video data and other sensory data, computational models that describe how an expert sonographer performs a diagnostic study of a subject from multiple perceptual cues. By understanding closely how experts learn and undertake diagnostic ultrasound, we believe that we will build considerably more powerful assistive video navigation and interpretation methods than have been possible so far. In PULSE we capture and record full-length routine ultrasound scan video; record probe movement; and track the point-of-gaze of the sonographer on the monitor of the ultrasound scanner.

All ultrasound scans included in this study were performed using a commercial Voluson E8 version BT18 (General Electric Healthcare, Zipf, Austria) ultrasound machine equipped with standard curvilinear (C2–9-D, C1–5-D), and 3 D/4 D (RAB6-D) probes. Synchronized eye tracking was undertaken using an eye tracker (Tobii Eye-tracking Eye Tracker 4C, Danderyd, Sweden) attached to the ultrasound machine. The validity of gaze-tracking has been previously validated [24].

This study was approved by the UK Research Ethics Committee (Reference 18/WS/0051), and written informed consent was given by all participating pregnant women. Sonographers also consented to participate in the study at the outset, but there was no visual or other signal to indicate that tracking devices were



▶ **Fig. 1** Output Display Standard (ODS) of the ultrasound safety bioeffect indices. Frame recorded during a routine scan. The ultrasound safety indices (TIs, TIb, MI), also known as the Output Display Standard (ODS), are displayed in real-time on the top right of the ultrasound image (red rectangle drawn around this for clarity. Patient identifiers as well as timestamp removed for anonymization).

activated. The PULSE project is funded by the European Research Council (grant ERC-ADG-2015 694 581)

Definitions and data extraction

The output display standard (ODS) is located on the upper right side of the screen, and it is where the ultrasound machine displays the TIb, TIs and MI values. The screen area around the TIb, TIs and MI values was defined as the ODS box (▶ **Fig. 1**).

Each scan was automatically analyzed on a video frame-by-frame basis with a purpose-built software program implemented in Python (www.python.org, version 3.7.0) using OpenCV (opencv.org, version 3.4) and Tesseract (github.com/tesseract-ocr, version 3.05). For each scan video, the software program detected the exam mode by unique features apparent in the different exam modes (i. e., color palette). The "measurement box" values and parameters were extracted via optical character recognition (OCR).

The GE Voluson E8 BT18 machine, by design, displays the TI as < 0.1 when energy emission is minimal. In the current analysis, for statistical purposes and because we were looking to ensure that safety is evaluated in a stringent approach when this happened values were recorded as 0.1.

For aim (3), we evaluated operator eye movements. Uninterrupted operator eye fixations on the "measurement box" of 100 ms or longer were detected automatically. Eye fixations that were 300 ms or less apart were classified as one fixation [25].

Outcomes

Our goals were 1) to evaluate the bioeffect safety indices in routine scans; 2) to evaluate the adherence to the AIUM and BMUS TI safety guidelines (▶ **Fig. 2**) [13, 14]; and 3) to determine how often operators look at the displayed bioeffect safety indices.

Statistics

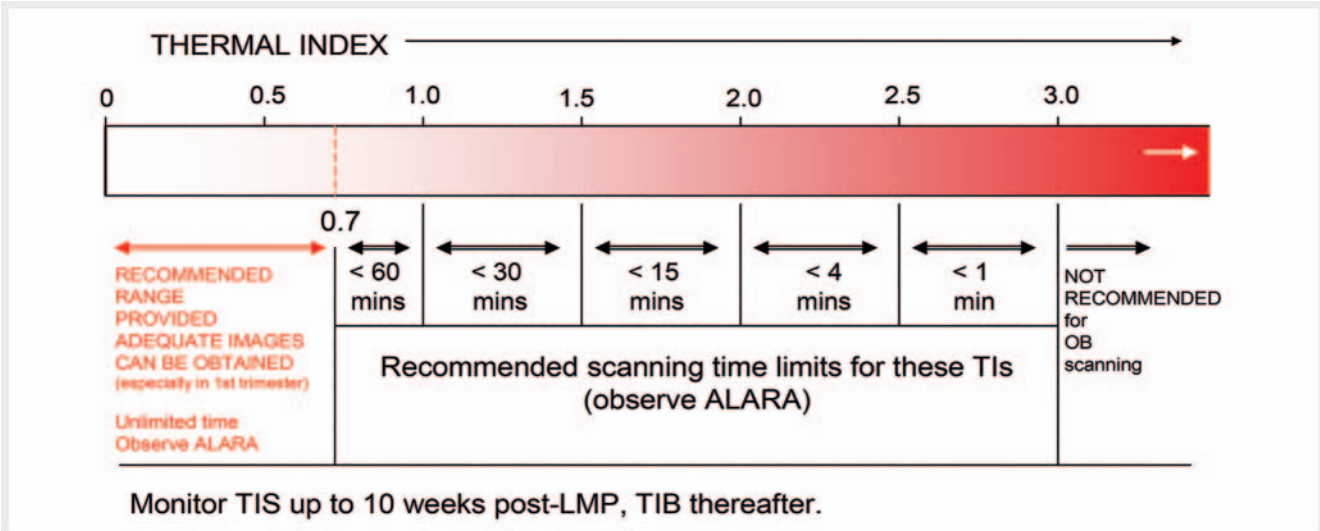
We report descriptive statistics. Analyses were carried out in Python (www.python.org, version 3.7.0), Pandas (pandas.pydata.org, version 0.24.0), SciPy (www.scipy.org, version 1.1.0), and Matplotlib (matplotlib.org, version 3.0.0).

Results

During the study period, a total of 637 women attending a routine obstetric scan agreed to our invitation to participate. 178, 216, and 243 ultrasound scans were performed in the first, second and third trimester, respectively. The scans were performed by 17 operators: 10 sonographers and 7 fetal medicine doctors. The demographic characteristics of the pregnant women and operators are given in ▶ **Table 1**.

The mean and standard deviation (SD) duration values of live scanning were 9.2 ± 6.5, 21.6 ± 11.1, and 7.2 ± 3.9 minutes for the first-trimester dating/NT, second-trimester anomaly, and growth scans, respectively.

During live scanning, the mean (range) first-trimester dating/NT scan TIb was 0.15 (0.1 to 2.1), TIs was 0.15 (0.1 to 1.2), and MI was 0.95 (0.1 to 1.3); the second-trimester anomaly scan TIb was 0.23



▶ **Fig. 2** Recommended maximum scanning times for displayed Thermal Index (TI) values according to the American Institute of Ultrasound in Medicine (AIUM) and the British Medical Ultrasound Society (BMUS). Adapted with permission of the British Medical Ultrasound Society (BMUS).

▶ **Table 1** Characteristics of 637 pregnant woman and 17 operators participating in this study.

maternal	
maternal age	31.7 ± 5.7
body Mass Index at < 15 weeks (kg/m2)	25.5 ± 5.5
gestational age at scan	
▪ first-trimester dating and NT scan	14.2 ± 7.7
▪ second-trimester anomaly scan	20.3 ± 0.5
▪ third-trimester growth scan	34.3 ± 3.3
operator	
gender	
▪ female	15 (88.2 %)
▪ male	2 (11.8 %)
years of experience	
▪ < 2 years	2 (11.8 %)
▪ 2–5 years	7 (41.2 %)
▪ 5–10 years	5 (29.4 %)
▪ > 10 years	2 (11.8 %)
accreditation	
▪ sonographer	10 (58.8 %)
▪ fetal medicine doctor	7 (41.2 %)

NT: Nuchal Translucency. Data are mean ± standard deviation or number (percent).

(0.1 to 2.6), TIs was 0.20 (0.1 to 1.2) and MI was 0.95 (0.1 to 1.3); and the third-trimester growth scan TIb was 0.32 (0.1 to 3.0), TIs was 0.24 (0.1 to 1.2) and MI was 0.91 (0.1 to 1.3). The bioeffect safety indices mean values and proportions for the different trimesters are shown in ▶ **Table 2**, ▶ **Fig. 3**.

For B-mode, the highest TIb was 0.8 in all trimesters. The highest TIb was recorded for pulsed wave Doppler mode in all trimesters. ▶ **Table 3** presents the TIb values according to the ultrasound mode (B-mode, color/power Doppler, and pulsed wave Doppler) for the different trimesters. The cumulative scanning time at or above a TIb value is presented in ▶ **Fig. 4**. There were 41 (23.0 %) first-trimester scans where the TIb was > 1.0. During the scans with TIb > 1.0, the average duration of TIb > 1.0 was 9.8 ± 7.6 seconds. The adherence to the AIUM and BMUS guidelines [13, 14] in all ultrasound modes combined according to the different trimesters are noted in ▶ **Table 4**. In all scans, regardless of trimester, the recommended exposure times were adhered to.

Eye tracking was successfully undertaken in all cases. This showed that the displayed bioeffect safety indices were looked at in 27 routine scans (4.2 %), by 4 of the 17 operators. In all 27 scans, we detected that the displayed bioeffect safety indices were checked once.

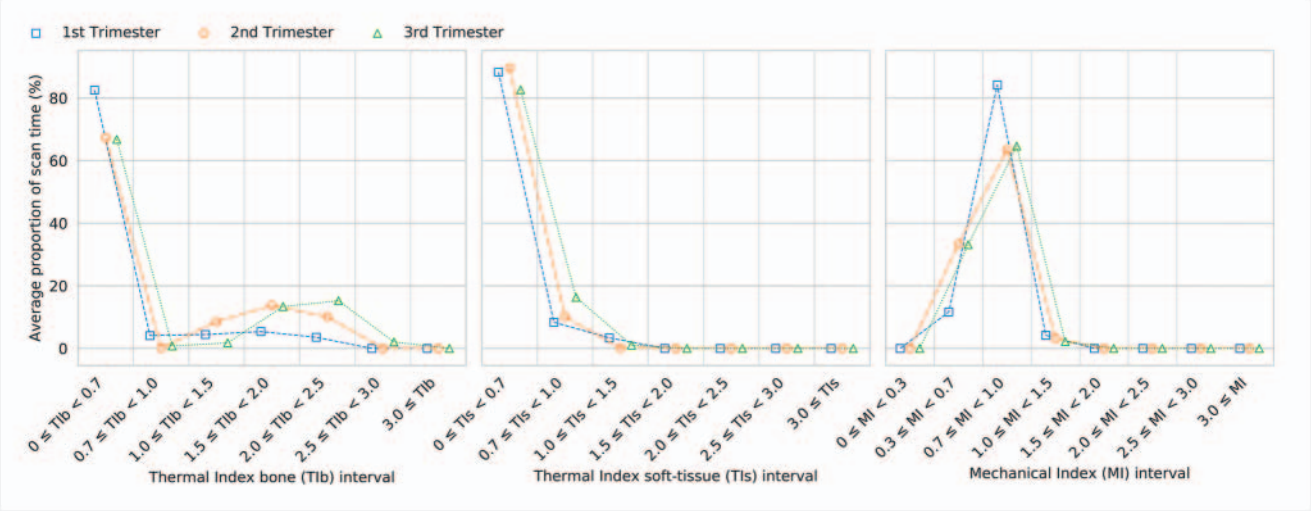
Discussion

In this paper, we report on the bioeffect safety indices (TIs, TIb, MI) for full-length routine obstetric scans as computed by automated analysis of video. We present results for all of the safety bioeffect indices (TIs, TIb, MI). However, it should be remembered that TIb is the most important bioeffect in pregnancies > 10 weeks of gestation. The recommended exposure times of TIb were kept in accordance with the current guidelines [13, 14]. Additionally, we found that operators infrequently visually checked the bioeffect indicators on the ultrasound machine display.

It is difficult to compare our results to previous publications since in previous studies the evaluation of operator adherence to safety recommendations in routine practice relied on saved still images [26, 27] and short cine-loops [28]. One study used entire tape-recorder scans. However, that study monitored a selected population of high-risk women in the second half of pregnancy only [29].

▶ **Table 2** Mean and maximal bioeffect safety indices measurements according to trimester.

	first trimester		second trimester		third trimester	
	mean ± SD	maximum	mean ± SD	maximum	mean ± SD	maximum
thermal Index for bone (TIb)	0.15 ± 0.03	2.1	0.23 ± 0.09	2.6	0.32 ± 0.24	3.0
thermal Index for soft tissue (TIs)	0.15 ± 0.01	1.2	0.20 ± 0.03	1.2	0.24 ± 0.05	1.2
mechanical Index (MI)	0.95 ± 0.01	1.3	0.95 ± 0.01	1.3	0.91 ± 0.02	1.3



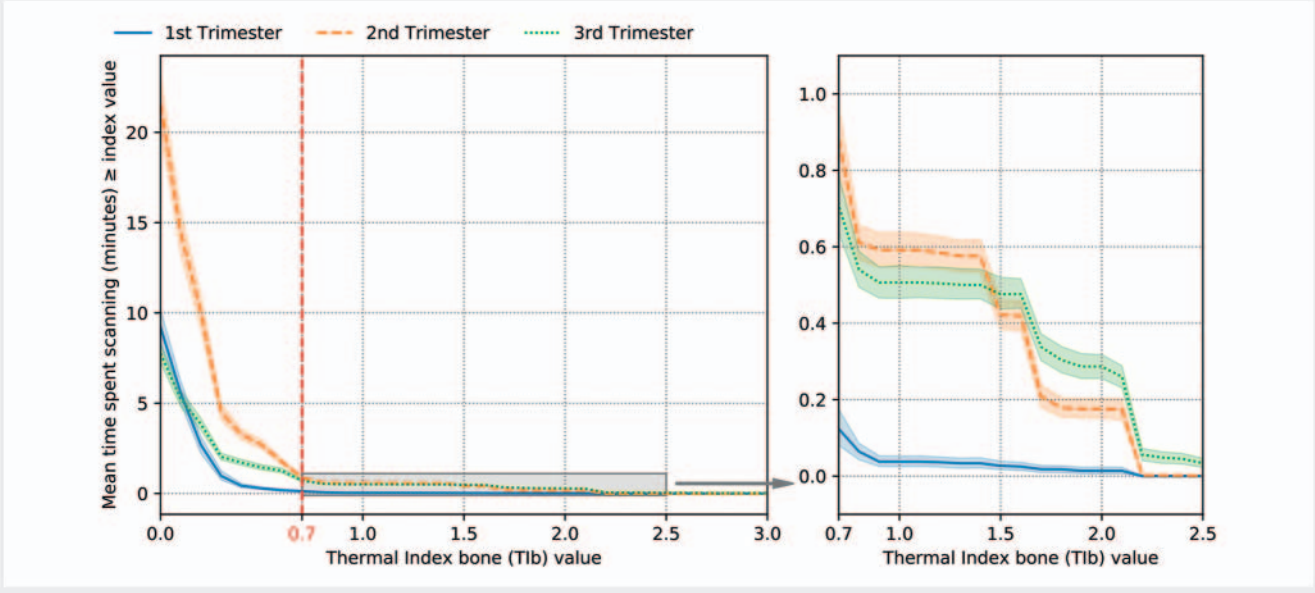
▶ **Fig. 3** Scanning time (mean proportion) for the three ultrasound bioeffect safety indices (TIb, TIs, MI) in the different trimesters.

▶ **Table 3** Mean and range of TIb values according to the ultrasound mode in the different trimesters.

	first trimester		second trimester		third trimester	
	mean ± SD	maximum	mean ± SD	maximum	mean ± SD	maximum
B-mode TIb	0.14 ± 0.01	0.8	0.15 ± 0.01	0.8	0.14 ± 0.01	0.8
Doppler (color/power) TIb	0.62 ± 0.01	0.8	0.53 ± 0.01	0.8	0.52 ± 0.01	0.8
pulsed wave Doppler TIb	1.65 ± 0.26	2.1	1.67 ± 0.1	2.6	1.89 ± 0.18	3.0

To simplify the approach to safe use of diagnostic ultrasound, the ALARA (As Low As Reasonably Achievable) principle has been proposed [8, 30]. ALARA encourages scans to be restricted to medical indications, by trained professionals, using the lowest intensity power and the shortest duration of scanning that is compatible with an accurate diagnosis. The International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) safety statement provides no absolute cutoffs for TI or MI, but states that "Exposure time and acoustic output should be kept to the lowest levels consistent with obtaining diagnostic information…" [31]. Hence, it is the responsibility of the operator to control the output energy safely. In addition to this general safety principle, the American Institute of Ultrasound in Medicine (AIUM) and the British Medical Ultrasound Society (BMUS) guidelines provide detailed recommendations for the maximum exposure duration depending on the TI value [13, 14].

We were able to show that in routine settings the thresholds recommended by the AIUM and BMUS are kept with good adherence to the recommended exposure times and were not exceeded even once. In first-trimester Doppler examinations, ISUOG recommends that the TI should not exceed 1.0 [19]. However, in our settings, pulsed wave Doppler is used only by some certified fetal medicine doctors in the first-trimester, and therefore, the ISUOG recommended TI was not always maintained. Nevertheless, the optimal TI value remains elusive in all trimesters, as it is not apparent that there is any particular threshold for thermally induced



▶ **Fig. 4** Cumulative scan time (mean and 95 % CI in minutes) at or above a Thermal Index in Bone (TIb) value in the different trimesters.

▶ **Table 4** Thermal Index bone (TIb) recommended and actual exposure times in 637 full length routine scans.

AIUM and BMUS recommendations		actual exposure time in 637 women					
		TIb first trimester		TIb second trimester		TIb third trimester	
TIb[1]	maximum exposure time (minutes)	mean ± SD	maximum	mean ± SD	maximum	mean ± SD	maximum
TIb ≤ 0.7	Unlimited	9.16 ± 6.37	35.2	21.0 ± 10.9	71.1	7.22 ± 3.93	28.3
0.7 < TIb ≤ 1.0	< 60	0.03 ± 0.10	0.84	0.02 ± 0.11	1.11	0.03 ± 0.17	1.56
1.0 < TIb ≤ 1.5	< 30	0.01 ± 0.05	0.30	0.17 ± 0.25	1.18	0.03 ± 0.10	0.76
1.5 < TIb ≤ 2.0	< 15	0.01 ± 0.03	0.24	0.24 ± 0.21	1.07	0.22 ± 0.25	1.58
2.0 < TIb ≤ 2.5	< 4	0.01 ± 0.06	0.40	0.17 ± 0.19	1.10	0.23 ± 0.24	1.31
2.5 < TIb ≤ 3.0	< 1	0.00 ± 0.00	0.00	0.00 ± 0.00	0.01	0.03 ± 0.10	0.57
TIb > 3.0	not recommended	0.00 ± 0.00	0.00	0.00 ± 0.00	0.00	0.00 ± 0.00	0.00

AIUM: American Institute of Ultrasound in Medicine; BMUS: British Medical Ultrasound Society. Figures are minutes.
[1] TIb should be used after 10 weeks of gestation (AIUM, BMUS guidelines[13, 14]).

damage [7]. Hence, users should adjust machine settings to obtain diagnostic images at the lowest possible acoustic output, recognizing that higher acoustic output does not necessarily improve image quality [32].

The "Output Display Standard" (ODS) should theoretically provide the necessary safety bioeffect indices information to the operator. However, there are concerns over its practicality [11]. Using eye tracking, we found that operators infrequently look at the safety bioeffect indices, including after freezing when the moving fetus no longer requires visual concentration. There may be several for this. It has been previously suggested that operators may not receive enough training regarding the safety of ultrasound or how to adjust the output level while keeping the same image quality [33]. However, one could also hypothesize that operators do not look at the indices as they feel that safety is a given and it is unnecessary to spend time monitoring the safety bioeffect indices [11]. There is some evidence from our study to suggest this is not unreasonable. Our results do suggest that bioeffect monitoring should be preliminarily done while using Doppler and this could be considered in future ultrasound safety guidelines. This is especially important while using pulsed-wave

Doppler since in routine settings [8] the TIb is as high as 2.1, 2.6, and 3.0 in the first, second, and third trimester, respectively.

In addition to aspects of operator awareness, there have been some reported concerns over the ability of the bioeffect indices to predict the intensity of ultrasound [17, 34]. This is because the bioeffect indices definitions have several weaknesses: TI and MI do not take into account practical imaging factors like a long fluid path (full bladder, polyhydramnios) or obesity, and the reported outputs are not necessarily equivalent to those calculated in the laboratory [17, 34].

Our study was limited by data collection at one maternity ward and using one set of equipment. Further research may be required to determine if the results can be generalized to other settings. This would be especially important to consider in settings where transvaginal ultrasonography is commonly used in the first trimester. Another potential limitation is the fact that the operators were aware of the eye-tracking component of the study which potentially could alter operator behavior. This is in contrast to our findings in a recent study in which we report that operators look at the biometric measurement values in over 90 % of scans [35]. However, it is unlikely that operators behaved differently. Since eye tracking is a passive measurement, operators do not have any visible indication of its function, and operators were not aware of the aims of the current analysis. Women included in this study had a mean BMI of 25.5 ± 5.5. In many regions of the world, the mean BMI is higher and the average time spent scanning in each modality may be higher. Lastly, the bioeffect safety indices values depend on the settings employed which depend on the mode selected, and these in-turn represent the default embedded during the machine setup. Nevertheless, this has probably not majorly altered our findings since operators commonly optimize machine settings in real-time. In the current analysis, we do not know whether machine settings adjustment was performed to improve the image quality or to optimize the machine energy output.

In conclusion, we have shown that in routine obstetric settings, safety indices are rarely looked at by operators. Despite this, the safety limits of ultrasound are adhered to. Our findings are reassuring since, despite years of concern, many operators still fail to demonstrate good knowledge of the bioeffects of ultrasound [11, 12]. Nevertheless, due to the potential adverse effects, ultrasound should be performed by trained personnel who have received ultrasound safety education.

Source of Funding

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Conflict of Interest

JAN and ATP are consultants to Intelligent Ultrasound Ltd but this work is not connected with their consultancy roles. The rest of the authors declare that they have no conflict of interest.

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